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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : A61L 15/58, C09J 133/08, 129/04, 139/06		A1	(11) International Publication Number: <b>WO 98/28024</b>
			(43) International Publication Date: 2 July 1998 (02.07.98)
(21) International Application Number: PCT/US97/23837			(74) Agents: REED, T., David et al.; The Procter & Gamble Company, 5299 Spring Grove Avenue, Cincinnati, OH 45217 (US).
(22) International Filing Date: 22 December 1997 (22.12.97)			
(30) Priority Data: 96120738.8 23 December 1996 (23.12.96) EP (34) Countries for which the regional or international application was filed: AT et al. 97110730.5 1 July 1997 (01.07.97) EP (34) Countries for which the regional or international application was filed: AT et al. 97120336.9 20 November 1997 (20.11.97) EP (34) Countries for which the regional or international application was filed: AT et al.			(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).
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(54) Title: ADHESIVE FOR SECURE TOPICAL ATTACHMENT TO THE SKIN AND COMFORTABLE REMOVAL			
(57) Abstract  The present invention relates to topical adhesives for attachment to the skin. In particular the present invention relates to such topical adhesives which can be employed for attachment to the skin of protective articles, clothing, prosthesis, heat wraps, pads, and/or packs, e.g. for topical relief of pain or simply to provide warmth; cold wraps, hearing aids, protective face masks, ornamental articles, or eye wear but excluding absorbent articles. The topical adhesive provides secure attachment and is pleasing to the skin upon application, yet causes no discomfort upon removal. This is achieved by selecting the chemical composition and rheological characteristics of the topical adhesives.			

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Adhesive for secure topical attachment to the skin and comfortable removal

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#### Field of the invention

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The present invention relates to topical adhesives for attachment to the skin. In particular the present invention relates to such topical adhesives which can be employed for attachment to the skin, particularly for the adhesion of protective articles such as genital-, knee- or elbow-protectors or bandages; clothing such as bras, surgical gowns, or parts of garments during fitting at a tailor; nasal plasters; prosthesis such as breast replacements or wigs; heat wraps, pads, and/or packs, e.g. for topical relief of pain or simply to provide warmth; cold wraps e.g. to provide pain relieve from bruises and to reduce swelling; hearing aids; protective face masks; ornamental articles such as jewelry, earrings, guises, tattoos; goggles or other eye wear. The topical adhesive provides secure attachment and is pleasing to the skin upon application, yet causes no discomfort upon removal. This is achieved by selecting the chemical composition and rheological characteristics of the topical adhesives.

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#### Background of the invention

The general prior art in the field of topical adhesives for attachment to the skin is particularly developed in the field of absorbent articles such as wound dressings, band-aids, plasters and bandages. These articles are, however, typically applied in an emergency situation where for example a cut into the skin of the wearer has occurred and absorption of the body liquids emanating from a wound is

desired. In this context performance aspects of the absorbent article such as comfortable and easy use and application, painless removal, discreteness are subordinate to criteria such as sterility, healing support, mechanical protection of the wound. Also such wound covering absorbent articles are mostly adhered to skin areas where prior to application of the absorbent article body hair can be removed or where little or no hair grows.

The present invention relates to topical adhesives which are particularly useful to protective articles such as genital-, knee- or elbow-protectors or bandages; clothing such as bras, surgical gowns, or parts of garments during fitting at a tailor; nasal plasters; prosthesis such as breast replacements or wigs; heat wraps, pads, and/or packs, e.g. for topical relief of pain or simply to provide warmth; cold wraps e.g. to provide pain relieve from bruises and to reduce swelling; hearing aids; protective face masks; ornamental articles such as jewelry, earrings, guises, tattoos; goggles or other eye wear. Such articles are not used for absorption of body liquids. For example attachment of a wig to the skin on the skull or of elbow and knee protectors to these surfaces of the body which undergo substantial extending and wrinkling can suitably be done by the adhesive of the present invention.

Topical adhesives which are used for absorbent articles such as sanitary napkins or pantliners have been disclosed in US statutory invention registration H1602 or WO 96/33683. Some more details of such adhesive have been disclosed in PCT application WO 95/16424. In this document sanitary articles having a topical adhesive which is applied on the wearer facing side of a sanitary napkin along the entire periphery are disclosed. The problem underlying this document is primarily the safe attachment to the skin but mentions also the problems of detachment of such articles after use without causing undue pain to a wearer.

The disclosure of WO 95/16424 includes a detailed analysis of the criteria for the topical adhesive in respect to rheological criteria. However, this document has little regard to the problem of painless removal of such articles since the rheological criteria taught include epilatory, i.e. hair removal, compositions which are commercially available such as STREP MIELE (TM) sold in Italy by Laboratori Vaj. S.p.A. The adhesives for topical attachment mentioned in WO 95/16424 include also today's pressure sensitive adhesives which are used to

attach sanitary napkins to undergarments. Further, this document only identifies static rheological characteristics but is silent as to the dynamic rheological behaviour of a topical adhesive.

- 5 In WO 96/13238 a frequency dependent topical adhesive model is disclosed. However, all measurements disclosed, e.g. on page 9, were made at temperatures between -60°C and +120°C and at actual frequencies of 0.1 to 100 rad/s. In order to obtain the necessary data at application temperature (about 20°C, typical bath room, i.e. storage temperature) the Williams-Landel-Ferry  
10 (hereinafter WLF) equation was used.

- This WLF equation is empirical and only valid within certain limits e.g. it cannot be used to extrapolate to temperatures below the glass transition temperature of a polymeric adhesive also the WLF cannot be used on the basis of values  
15 obtained below the glass transition temperature. Details about the WLF equation and its applicability can be found in "Principles of Polymer processing" by Z. Tadmor and C.G. Gogos, published by John Wiley & Sons or in "Viscoelastic Properties of Polymers" by J.D. Ferry also published by John Wiley & Son. Since this is already missing from WO 96/13238 the applicability of the disclosed data  
20 cannot be assessed.

- Based on the above state of the art it is an objective of the present invention to provide a topical adhesive for secure attachment and painless removal from the skin for articles outside the absorbent article field . It is another objective of the  
25 present invention to ensure upon removal that no residual adhesive remains on the skin or on the hair.

- It is yet a further objective of the present invention that the adhesive for topical attachment does not cause a cold or otherwise unacceptable temperature  
30 sensation upon application despite a temperature difference of the adhesive in respect to the skin temperature.

- In addition to the above objectives of the present invention it is also desirable for topical adhesives to provide additional benefits such as delivery/ dispersal of a  
35 compound or composition which is beneficial for the skin or for the body in

general. Further, topical adhesives which do not affect the natural skin condition/ e.g. by being breathable or water vapour transmitting are preferred.

Brief description of the invention

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The present invention is useful to attach to the skin or wear protective articles such as genital-, knee- or elbow-protectors or bandages; clothing such as bras, surgical gowns, or parts of garments during fitting at a tailor; nasal plasters; prosthesis such as breast replacements or wigs; heat wraps, pads, and/or packs, 10 e.g. for topical relief of pain or simply to provide warmth; cold wraps e.g. to provide pain relieve from bruises and to reduce swelling; hearing aids; protective face masks; ornamental articles such as jewelry, earrings, guises, tattoos; goggles or other eye wear. Such articles are non-absorbent for bodily liquids. The article typically has a wearer facing surface and an outside surface. The 15 topical adhesive allows secure attachment of an article to the skin of the wearer.

Detailed analysis of the sequence of common situations occurring from the application of a disposable absorbent article to the time of removal of such an article has shown that specific adhesive characteristics need to be satisfied in 20 order to achieve the desired performance objectives, in particular secure initial attachment, secure attachment during use and painless removal at the end. The characteristics which have been considered in this context are the elastic modulus describing the elastic behaviour of the material and the viscous modulus which describes the viscous behaviour of the adhesive material.

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The viscous behaviour of the adhesive can be interpreted to represent an indication of the ability of the adhesive to quickly attach and securely adhere. The elastic behaviour can be interpreted as an indication of the "hardness" behaviour of the adhesive. Its value is also critical for good initial attachment. 30 Their combination is believed to be an indicator of the required force upon removal. The relation between elastic and viscous modulus is considered to be an indication which fraction of the removal energy will be dissipated within the adhesive and which fraction is available to trigger the actual removal.

In order to provide topical adhesives for secure initial and prolonged attachment and easy/painless removal the relation between the elastic modulus and the viscous modulus as well as their dynamic behaviour is of key importance.

- 5 The topical adhesive has an elastic modulus at a temperature of 37°C (100° Fahrenheit) abbreviated  $G'_{37}$  and a viscous modulus at a temperature of 37°C (100° Fahrenheit) of  $G''_{37}$ . The adhesive further has a dynamic elastic behaviour defined as  $\Delta G'_{37}$  which is the difference of  $G'_{37}$  at a frequency of 100 rad/sec and  $G'_{37}$  at a frequency of 1 rad/sec and a dynamic viscous behaviour  $\Delta G''_{37}$  which is the difference of  $G''_{37}$  at a frequency of 100 rad/sec and  $G''_{37}$  at a frequency of 1 rad/sec.

The topical adhesive according to the present invention satisfies the following conditions.

- 15
- $G'_{37}$  (1 rad/sec) is in the range 1500 Pa to 20000 Pa, preferably 1500 Pa to 15000 Pa, most preferably 3000 Pa to 10000 Pa.
  - 20 •  $G''_{37}$  (1 rad/sec) is in the range 100 Pa to 15000 Pa, preferably 100 Pa to 10000 Pa, most preferably 300 Pa to 5000 Pa.
  - the ratio of  $G'_{37}$  (1 rad/sec) /  $G''_{37}$  (1 rad/sec) is in the range of 3 to 30.
  - 25 • the ratio
- $$\frac{G'_{37} (100 \text{ rad/sec}) - G''_{37} (100 \text{ rad/sec})}{G'_{37} (1 \text{ rad/sec}) - G''_{37} (1 \text{ rad/sec})}$$
- 30 is not less than 0.5, preferably in the range 0.7 to 3, most preferably in the range 1 to 1.8.
- 35 • either the ratio of  $\Delta G'_{37}/G'_{37}$  (1 rad/sec) is not greater than 1.5, preferably not greater than unity and most preferably not greater than 0.8,

or  $\Delta G'_{37}$  is not greater than 10000 Pa, preferably less than 5000 Pa, most preferably less than 2000 Pa,  
or both.

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- the value of the ratio  $G'_{37}/G''_{37}$  at least for the frequency range from above 1 rad/s up to 100 rad/s should preferably 3.3 or above, more preferably 5 or above, most preferably 10 or above while not exceeding about 50, preferably 30, anywhere in the frequency interval.

10

- the rheological behaviour can also be related to the values of the Glass Transition Temperature  $T_g$ . For topical adhesives according to the present invention  $T_g$  should preferably be less than  $-15^{\circ}\text{C}$ , more preferably less than  $-20^{\circ}\text{C}$  and most preferably less than  $-25^{\circ}\text{C}$ .

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- the rheological behaviour and acceptance of a topical adhesive can also be related to the specific heat capacity. Preferably the specific heat capacity of the topical adhesive is less than 4 J/g/K, more preferably less than 3 J/g/K and most preferably less than 2 J/g/K.

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- the rheological behaviour and acceptance of a topical adhesive can also be related to the specific heat conductivity of the adhesive. Preferably the specific heat conductivity is as low as possible, preferably between 1 and 0.1 W/m/K, most preferably between 0.6 and 0.1 W/m/K. However, even so these ranges allow selection of appropriate adhesives, in the case of cooling or heating pads it is desirable to have a relatively high value of heat conductivity to support the function of such articles.

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Provided the above rheological conditions are satisfied the adhesives will also satisfy conditions such as sufficient cohesiveness (to prevent residue of adhesive on skin) which are critical for commercial use of such adhesives and apparent to those skilled in the art. Adhesive compositions which satisfy the above criteria can be used as topical adhesives for the above mentioned articles provided they also satisfy the common requirements of being safe for use on human or animal skin during use and generally after disposal.

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Often the criteria of hygienic appearance and pleasant feel upon contact are important such that adhesive composition which are transparent or white, and which prevent a cold, unpleasant feeling upon application are preferred.

- 5 The above rheological criteria and other considerations can be satisfied by adhesive compositions where the composition comprises from 45%, preferably from 51 %, to 99.5 % of a plasticising compound or composition which is liquid at 20°C, from 0.5 to 20 %, preferably 5 % to 15 %, of a polymeric compound or composition which is soluble or swellable in the plasticising compound or composition and with a tackifying resin in an amount in the range from 0 % to 50 % by weight of the composition, preferably from 0 % to 600 % by weight of the polymeric compound. The plasticising compound or composition is preferably selected from the group consisting of water, alcohols (preferably glycerol), glycols, polyglycols, liquid polybutenes, oil or combinations thereof. The polymeric compound or composition is preferably selected from the group consisting of polyacrylics, polyvinylalcohol, natural gum or gelatines, polyethyleneoxide, polyvinylpyrrolidone (PVP), polyvinylethers, cellulose derivatives, or combinations thereof.

#### Detailed description of the invention

##### Adhesive for topical attachment

The topical adhesive according to the present invention is applied directly to the skin. In a particular application the adhesive can be used on protective articles such as genital-, knee- or elbow-protectors or bandages; clothing such as bras, surgical gowns, or parts of garments during fitting at a tailor; nasal plasters; prosthesis such as breast replacements or wigs; heat wraps, pads, and/or packs, e.g. for topical relief of pain or simply to provide warmth; cold wraps e.g. to provide pain relieve from bruises and to reduce swelling; hearing aids; protective face masks; ornamental articles such as jewelry, earrings, guises, tattoos; goggles or other eye wear. The word "skin" according to the present invention does relate to the outer surface of the derma of humans or animals.

In order to provide fixation of an article according to the present invention to the skin it is necessary to provide a certain area on the side of the article which is facing the skin with the topical adhesive.

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Physical, Rheological and Adhesive Characteristics of a Topical Adhesive

Even so topical adhesives are used like pressure sensitive adhesives on human or animal skin, it is understood that the topical adhesive compositions could only with difficulty be considered typical pressure sensitive adhesives (referred to as PSA hereinafter) on the basis of the most characteristic rheological behaviours identifying such materials.

In fact as the person skilled in the art of adhesives knows, the most characteristic feature that distinguish a PSA from other substances that can temporarily stick things (as e.g. water between two glass plates could) is the fact that their rheological parameters and especially the Elastic Modulus  $G'$  vary greatly with the frequency of applied stresses. More in particular,  $G'$  of PSA can increase over some orders of magnitude while the frequency of applied stresses varies from typical bonding frequency to typical debonding frequency, i.e. 1 rad/s to 100 rad/s as indicated below.

As a first consequence, it derives that it is inadmissible to define materials intended for use as "topical adhesives" by giving values of rheological parameters and especially of  $G'$  at a fixed value of frequency. This can be misleading because in the absence of other characteristics it will include materials which have no practical value. It is hence necessary that rheological characterisation must be on the base of dynamic considerations.

This not only applies to the Elastic Modulus  $G'$  but also to the viscous modulus  $G''$  and hence also for  $\tan(\delta) = G'' / G'$ . It is well known that typical PSA have not only a high variation of  $G'$  across the considered frequencies but also there is an even higher variation of  $G''$  which can get close or become even higher than the value of  $G'$ , i.e.  $\tan(\delta)$  becomes about or even greater than 1, in particular at the frequencies that are typical of the debonding.

Without wishing to be bound by theory this can be interpreted as meaning that a high fraction of the energy applied for the debonding is dissipated within the adhesive (so it is not effective in causing the debonding) while this fact causes macroscopically the recording of a very high level of adhesive force.

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As indicated above materials useful as topical adhesives according to the present invention have rheological characteristics which are measured at a reference temperature of 37°C (as usual body temperature of humans) and in a range of frequencies. It has been found that upon application of an article such as a wig with a topical adhesive the adhesive contact is formed at a low frequency, while debonding happens at the speed of removing the article. This speed is expressed as a frequency of 100 rad/s while the low frequency of forming the adhesive bond has been found to be on the order of 1 rad/s. Therefore, the frequency range for use according to the present invention is between 1 and 100 rad/s.

15

It is believed that the adhesive bonding characteristics are selected most appropriately at human body temperature. Since the topical adhesive according to the present invention is used directly on skin and the person skilled in the art is directed to select the adhesive composition to have a small specific heat capacity (e.g. preferably less than 4 J/g/K) the actual temperature of the topical adhesive will reach 37°C very quickly or even be warmed up by a human prior to application.

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In order to provide good conditions of bonding, i.e. at a frequency of about 1 rad/sec, the absolute values of the elastic modulus should not be too high, otherwise the adhesive is too hard and it is not able to intimately join or mold to the surface to which it is expected to adhere. It is also important to have a low absolute value of  $G''$  in order to have good cohesion which is particularly valuable, when using articles which are frequently removed and adhered again or replaced while the material remains soft and capable of gently adhering to skin.

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The ratio of  $G'_{37}$  (1 rad/sec) over  $G''_{37}$  (1 rad/sec) is important to ensure that these two values are balanced upon adhesion to the skin. At the same time the absolute changes of  $G'_{37}$  needs to be limited within the range of frequencies

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considered. Hence a value for the ratio of  $\Delta G'_{37}$  (i.e.  $G'_{37}$  (100 rad/sec) -  $G'_{37}$  (1 rad/sec)) over  $G'_{37}$  (1 rad/sec) has to be kept small in order to maintain the secure attachment of the topical adhesive without causing discomfort over time or at removal/ delamination. This can also be expressed in absolute terms by  
 5 keeping the  $\Delta G'_{37}$  below certain values.

Importantly, the ratio of 
$$\frac{G'_{37} (100 \text{ rad/sec}) - G''_{37} (100 \text{ rad/sec})}{G'_{37} (1 \text{ rad/sec}) - G''_{37} (1 \text{ rad/sec})}$$
  
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needs to be large enough to ensure that the dynamic behaviour of both the elastic and the viscous module are maintained in a relationship which provides secure adhesion and painless and easy removal.

15 Finally the person skilled in the art will also recognise that the Glass Transition Temperature  $T_g$  of the adhesive composition, specific heat capacity, and specific heat conductivity are parameters which are useful to more fully define the group of useful topical adhesives.

20 The following set of characteristics should be satisfied:

•  $G'_{37}$  (1 rad/sec) is in the range 1500 Pa to 20000 Pa,  
 preferably 1500 Pa to 15000 Pa, most  
 25 preferably 3000 Pa to 10000 Pa.

•  $G''_{37}$  (1 rad/sec) is in the range 100 Pa to 15000 Pa,  
 preferably 100 Pa to 10000 Pa, most  
 preferably 300 Pa to 5000 Pa.

30 • the ratio of  $G'_{37}$  (1 rad/sec) /  $G''_{37}$  (1 rad/sec) is in the range of 3 to 30.

35 • the ratio 
$$\frac{G'_{37} (100 \text{ rad/sec}) - G''_{37} (100 \text{ rad/sec})}{G'_{37} (1 \text{ rad/sec}) - G''_{37} (1 \text{ rad/sec})}$$
  
 is not less than 0.5, preferably in the range

0.7 to 3, most preferably in the range  
1 to 1.8.

- 5       • either the ratio of  $\Delta G'_{37}/G'_{37}$  (1 rad/sec) is not greater than 1.5,  
preferably not greater than unity and most preferably  
not greater than 0.8,

- 10       or  $\Delta G'_{37}$  is not greater than 10000 Pa, preferably less  
than 5000 Pa, most preferably less than 2000 Pa,  
or both.

- 15       • the value of the ratio  $G'_{37}/G''_{37}$  at least for the frequency range from above 1  
rad/s up to 100 rad/s should preferably be 3.3 or above, more preferably 5 or  
above, most preferably 10 or above while not exceeding about 50, preferably 30,  
anywhere in the frequency interval.

- 20       • the rheological behaviour can also be related to the values of the Glass  
Transition Temperature  $T_g$ . For topical adhesives according to the present  
invention  $T_g$  should preferably be less than  $-15^{\circ}\text{C}$ , more preferably less than  $-$   
20  $20^{\circ}\text{C}$  and most preferably less than  $-25^{\circ}\text{C}$ .

- 25       • the rheological behaviour and acceptance of a topical adhesive can also be  
related to the specific heat capacity. Preferably the specific heat capacity of the  
topical adhesive is less than 4 J/g/K, more preferably less than 3 J/g/K and most  
preferably less than 2 J/g/K.

- 30       • the rheological behaviour and acceptance of a topical adhesive can also be  
related to the specific heat conductivity of the adhesive. Preferably the specific  
heat conductivity is as low as possible (except for energy transmitting articles  
where high values are more desirable), more preferable between 1 and 0.1  
W/m/K, most preferably between 0.6 and 0.1 W/m/K.

#### Chemical and compositional characteristics of a Topical adhesive

- 35       In order to provide topical adhesive compositions which satisfy the requirements  
of the above rheological and physical characteristics of a topical adhesive the

following formulation criteria can be used in addition. It should be noted that the most of the compositions useful as topical adhesive have a substantially gel-like structure and are preferably gels. This derives from the fact that:

5 - the prevailing component is the plasticiser which is a material liquid at room temperature

- a macromolecular or polymeric component is present in minor quantities vs the plasticiser. It forms, in the preferred embodiments, a three dimensional network  
10 caused by physical or chemical links between the molecules. Particularly useful physical links are the ones present in systems containing Block Thermoplastic Elastomers.

More specifically, the compositions typically comprise:

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- from 0.5 to 20 %, preferably 5 % to 15 %, by weight of a macromolecular polymeric substance or a mixture of such substances soluble or swellable in the below mentioned plasticiser(s). As not limiting examples such macromolecular or polymeric substances can be natural and/or synthetic such as natural gums or  
20 derivatives such as natural gums and gelatines, their derivatives and alginates; polyacrilics; polyvinyl alcohol; polyethylene oxide; polyvinylpyrrolidon (PVP) or polyvinylethers, their copolymers and derivatives; cellulose derivatives; Block Copolymer Thermoplastic Elastomers and preferably Styrenic Block Copolymers and more preferably the hydrogenated grades Styrol/Ethylene-Butylene/Styrol  
25 (SEBS), Styrene/Isoprene/Styrene (SIS), and Styrol/Ethylene-Propylene/Styrol (SEPS).

- from 45 to 99.5 % by weight, preferably from 51 to 99.5% by weight, of a plasticising substance or a mixture of plasticising substances, which are liquid at  
30 room temperature. As non-limiting examples the plasticiser can be water, various alcohols (like in particular glycerol), glycols and their ethers, polyglycols, liquid polybutenes, esters such phtalates, adipates, stearates, palmitates, sebacates, or myristates, natural or synthetic oils such as vegetable oils, mineral oils, or combinations thereof.

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- from 0 % to 50 % by weight of the composition, preferably 0 % to 600 % by weight of the macromolecular polymeric substance, of a tackifying resin whose main scope is to tailor the Tg especially in systems based on synthetic polymers.

- 5 - from 0 to 10 % and more preferably from 0 to 5 % by weight of substances for facilitating and stabilising the gel and the gel forming process both of hydrophilic or hydrophobic liquid plasticisers. These may be for oily systems, e.g. the fatty acids of C<sub>8</sub> to C<sub>22</sub>, their metallic salts and their polyoxo-derivatives; lanolin derivatives; silica; bentonite, montmorillonite and their derivatives; polyamides,  
10 waxes or mixtures thereof.

Common additives known in the art as preservatives, antioxidants, anti UV, pigments, mineral fillers, rheology modifiers etc. can also be comprised in quantities up to 10 % each.

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When chemical crosslinks are formed in the system, a crosslinking agent can be present preferably in quantities up to 5 % by weight. Chemical crosslinking can be formed also by mutual neutralisation of polymers having different functionalities as in the reaction between acid polyacrylics and polysaccharides.

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The resulting compositions for topical adhesives can be divided into three families according to the nature of the main component, i.e. usually the liquid plasticiser(s):

- 25 1) Hydrophobic compositions in which the plasticiser is typically an oil or blend of oils of vegetable or mineral origin and the polymer is usually a synthetic polymer, preferably an elastomer, soluble or swellable in oil(s).
- 2) Mixed phase compositions in which both hydrophobic and hydrophilic components, possibly in both plasticisers and polymers, form two or more  
30 separate phases. In such cases an emulsifier/surfactant is preferably present at a suitable level to form stable emulsions between the incompatible phases. For topical adhesives according to the present invention it is preferable that the hydrophilic components are prevailing vs. the hydrophobic ones.
- 3) Hydrophilic compositions in which typically the plasticiser is  
35 water/glycerol/glycols and the like and/or mixtures thereof and the polymeric

phase is of synthetic (e.g. polyacrilics) or natural (e.g. natural gums) origin or mixtures thereof.

5 It is to stress that, differently from the field of absorbent articles the hydrophilic and mixed phases compositions are preferred while the hydrophobic, adhesives are less preferred in the applications of the present invention.

10 This depends partially on the reason that topical adhesives in absorbent products in particular for sanitary napkins, have a probability of contacting the liquid to be absorbed. Since wound liquids or bodily discharge liquids are all of a general aqueous kind contact with a hydrophilic topical adhesive would result in a certain absorption of the bodily liquids into the topical adhesives. Since this is not the case for the topical adhesives for non-absorbent articles, this limitation does not need to be observed. However, a hydrophilic topical adhesive is  
15 preferable for many well-known reasons including e.g. the better skin compatibility and water vapour transmission ability.

#### Application of topical adhesive

20 Articles, comprising the topical adhesive according to the present invention can be used and can be made by any of the ways usual in the art. The application of the adhesive to the skin facing side of such articles should not cause major problems to those skilled in the art since it can be provided by any well known techniques commonly used for other adhesives. The total area of the skin facing  
25 surface of an article which is covered by the topical adhesive depends on its intended use. For conservation of adhesive it should be not more than 80 %, preferably from 30 % to 60 % of the wearer facing surface. Preferably, the adhesive extends close to the periphery of the article but since it is not intended for absorbent articles it can also cover the central area of the articles. Most  
30 preferably the adhesive is provided in a pattern of small incremental areas such as dots or similar.

The topical adhesive on an article is preferably protected prior to use. This protection can be provided by a release liner such as a treated paper, providing  
35 easy release for the selected topical adhesive.



If possible, the article also provides breathability by being at least water vapour permeable, preferably air permeable to prevent stuffiness. Breathability, if not supported by the topical adhesive as such, can be limited to the area of the article where no adhesive is applied.

5

### EXAMPLE 1

An oil based composition according to the present invention was prepared using  
10 9.9 % by weight of Kraton G-1651, a Styrene/Ethylene-Butylene/Styrene block copolymer containing 33% by weight styrene and available from Shell Co, and 59.3 % by weight of Kaydol, a paraffinic mineral oil available from Witco Co.

Moreover the composition contained 301 parts of tackifying resin per 100 parts of  
15 Kraton polymer. The tackifying resin was Escorez 5300, a hydrogenated resin available from Exxon Co.

Magnesium Stearate, available from Carlo Erba S.p.A., was used a co-gelifying agent for oil at a level of 0.7 % by weight.

20

Irganox 1010, an antioxidant available from Ciba-Geigy, was added at a level of 0.3 % by weight.

So finally the formulation had the following percent composition:

25

Kraton G-1651	9.9 % by weight
Kaydol	59.3 % by weight
Escorez 5300	29.8 % by weight
Magnesium Stearate	0.7 % by weight
30 Irganox 1010	0.3 % by weight

The composition showed the following rheological properties at 37°C.

- a) Elastic Modulus at 1 rad/s,  $G'_{37} = 6876 \text{ Pa}$   
35 b) Viscous Modulus at 1 rad/s,  $G''_{37} = 550,5 \text{ Pa}$   
c) Ratio of Elastic and Viscous Modulus at 1 rad/s,  $G'_{37} / G''_{37} = 12.49$

d) Ratio of

$$\frac{G'_{37} (100 \text{ rad/sec}) - G''_{37} (100 \text{ rad/sec})}{G'_{37} (1 \text{ rad/sec}) - G''_{37} (1 \text{ rad/sec})}$$

5 = 1.22

e) The ratio of  $\Delta G'_{37}$  over  $G'_{37}$  (1 rad/s) was 0.308,  
with  $\Delta G'_{37} = 2124 \text{ Pa}$ .

10

The above formulation was tried and judged as comfortable for initial application and removal from sensitive, hairy skin.

#### COMPARATIVE EXAMPLE

15 A comparative oil based composition was compounded using 7.1 % by weight of Kraton G-1651, a Styrene/Ethylene-Butylene/Styrene block copolymer containing 33% by weight styrene and available from Shell Co, and 41.9 % by weight of Kaydol, a paraffinic mineral oil available from Witco Co.

20 Moreover the composition contained 704 parts of tackifying resin per 100 parts of Kraton polymer. The tackifying resin was Regalrez 3102, a hydrocarbon resin available from Hercules Co.

25 Magnesium Stearate, available from Carlo Erba S.p.A., was used a co-gelifying agent for oil at a level of 0.7 % by weight.

Irganox 1010, an antioxidant available from Ciba-Geigy, was added at a level of 0.3 % by weight.

30 So finally the formulation had the following percent composition:

Kraton G-1651	7.1 % by weight
Kaydol	41.9 % by weight
Regalrez 3102	50.0 % by weight
35 Magnesium Stearate	0.7 % by weight
Irganox 1010	0.3 % by weight

The composition showed the following rheological properties at 37°C.

- a) Elastic Modulus at 1 rad/s,  $G'_{37} = 3059 \text{ Pa}$
  - b) Viscous Modulus at 1 rad/s,  $G''_{37} = 1208 \text{ Pa}$
  - 5 c) Ratio of Elastic and Viscous Modulus at 1 rad/s,  $G'_{37} / G''_{37} = 2.53$
  - d) Ratio of  $G'_{37} (100 \text{ rad/sec}) - G''_{37} (100 \text{ rad/sec})$
- 
- 10  $G'_{37} (1 \text{ rad/sec}) - G''_{37} (1 \text{ rad/sec})$   
 $= - 2.87$
- e) The ratio  $\Delta G'_{37}$  over  $G'_{37} (1 \text{ rad/s})$  was 3.944  
 with  $\Delta G'_{37} = 12064.7 \text{ Pa}$ .
  - 15 The above formulation was judged as highly uncomfortable for delamination from  
 fore-arm skin. Application to sensitive hairy skin was unacceptable.

## Claims

- 5 1.) A topical adhesive for attachment of protective articles, clothing, prosthesis, heat wraps, ice wraps, hearing aids, protective face masks, ornamental articles or eye wear to the skin, but excluding disposable absorbent articles such as wound dressings, sanitary napkins, pantliners, incontinence articles or underarm sweat pads,
- 10 - said adhesive having an elastic modulus at a temperature of 37°C (100°F), G'37, and having a viscous modulus at a temperature of 37°C (100°F), G"37,
- said adhesive being selected to have
- 15 • G'37 (1 rad/sec) in the range 1500 Pa to 20000 Pa, preferably 1500 Pa to 15000 Pa, most preferably 3000 Pa to 10000 Pa;
- G"37 (1 rad/sec) in the range 100 Pa to 15000 Pa, preferably 100 Pa to 10000 Pa, most preferably 300 Pa to 5000 Pa;
- 20 • the ratio G'37 (1 rad/sec) / G"37 (1 rad/sec) is in the range 3 to 30;
- the ratio
- 25 
$$\frac{G'_{37} (100 \text{ rad/sec}) - G''_{37} (100 \text{ rad/sec})}{G'_{37} (1 \text{ rad/sec}) - G''_{37} (1 \text{ rad/sec})}$$
- is not less than 0.5, preferably in the range 0.7 to 3, most preferably in the range 1 to 1.8;
- 30 • alternatively either
- G'37 (100 rad/sec) - G' (1 rad/sec) is not greater than 10000 Pa, preferably less than 5000 Pa, preferably less than 2000 Pa;
- 35 or

- the ratio  $\frac{G'_{37} (100 \text{ rad/sec}) - G'_{37} (1 \text{ rad/sec})}{G'_{37} (1 \text{ rad/sec})}$

5 is not greater than 1.5, preferably not greater than 1, most preferably not greater than 0.8,

or a combination thereof.

10 2. A topical adhesive according to claim 1 wherein the value of the ratio  $G'_{37}$  over  $G''_{37}$  in the frequency range 1 - 100 rad/s is in the range 3.3 to 50, preferably 3.3 to 30.

15 3. A topical adhesive according to any of the preceding claims comprising

- from 45 % to 99.5 %, preferably from 51 % to 99.5 %, by weight of a plasticising compound or composition which is liquid at 20°C;

20 - from 0.5 % to 20 % by weight of a polymeric compound or composition which is solvable or swellable in said plasticising compound or composition;

- a tackifying resin in an amount of from 0 % to 50 % by weight, preferably from 0 % to 600 % by weight of said polymeric compound or composition.

25 4. A topical adhesive according to claim 3 wherein

- said plasticising compound or composition is selected from the following group: water, alcohols, glycols, oil or combinations thereof; and

30 - said polymeric compound or composition is selected from the following group: polyacrylics, polyvinylalcohol, natural gum or gelatines, polyethyleneoxide, polyvinylpyrrolidone (PVP), polyvinylethers, cellulose derivatives, or combinations thereof.

5. A topical adhesive according to any of the preceding claims wherein 80 % by weight of said adhesive consist of hydrophilic components and most preferably all components of said adhesive are hydrophilic.
- 5 6. A topical adhesive according to any of the preceding claims wherein said adhesive has a glass transition temperature of less than  $-15^{\circ}\text{C}$ , preferably less than  $-20^{\circ}\text{C}$ , most preferably  $-25^{\circ}\text{C}$ .
- 10 7. A topical adhesive according to any of the preceding claims wherein said adhesive has a specific heat capacity of less than  $4 \text{ J/g/K}$ , preferably less than  $3 \text{ J/g/K}$ , most preferably less than  $2 \text{ J/g/K}$ .
- 15 8. A topical adhesive according to any of the preceding claims wherein said adhesive has a specific heat conductivity of less than  $1 \text{ W/m/K}$ , preferably in the range of  $0.1$  to  $1 \text{ W/m/K}$ , most preferably in the range of  $0.1$  to  $0.6 \text{ W/m/K}$ .
- 20 9. Use of a topical adhesive according to any of the preceding claims on protective articles, clothing, prosthesis, heat wraps, pads, and/or packs, cold wraps, hearing aids, protective face masks, ornamental articles, eye wear or make-up.

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 97/23837

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61L15/58 C09J133/08 C09J129/04 C09J139/06

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61L A61K C09J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 93 10201 A (MINNESOTA MINING & MFG) 27 May 1993 see page 2, line 27 - line 38 see page 4, line 31 - line 41 see page 7, line 1 - page 9, line 27 ---	1,3-5,9
X	FR 2 734 574 A (PACIFIC CORP) 29 November 1996 see page 4, line 21 - page 6, line 26 see page 7, line 15 - page 9, line 9 see claims; examples ---	1,3,4,9
X	GB 2 115 431 A (VALLEYLAB INC) 7 September 1983 see page 4, line 55 - page 5, line 14 see page 5, line 47 - page 7, line 13 see page 10, line 6 - line 28 see page 11, line 10 - line 19 ---	3-5,9
-/--		

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents :

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search

29 April 1998

Date of mailing of the international search report

11/05/1998

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# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 97/23837

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 184 470 A (MEDTRONIC INC) 11 June 1986 see page 3, line 10 - line 19 see page 3, line 34 - page 5, line 7 ----	3-5
X	PATENT ABSTRACTS OF JAPAN vol. 004, no. 144 (C-027), 11 October 1980 & JP 55 092306 A (NITTO ELECTRIC IND CO LTD), 12 July 1980, see abstract ----	1,3,4,9
X	PATENT ABSTRACTS OF JAPAN vol. 012, no. 070 (C-479), 4 March 1988 & JP 62 209008 A (NIKKO KEMIKARUZU KK;OTHERS: 01), 14 September 1987, see abstract ----	1,3,4,9
Y	WO 96 14822 A (OSMOTICS CORP) 23 May 1996 see page 9, line 13 - line 28 see page 13, line 1 - page 14, line 23 ----	1-9
Y	WO 96 13238 A (KIMBERLY CLARK CO) 9 May 1996 cited in the application see page 7, line 11 - page 10, line 6 see page 2, line 15 - line 35 see claims; examples 1-4 ----	1-9
A	US 5 559 165 A (PAUL CHARLES W) 24 September 1996 see column 1, line 21 - line 35 see column 1, line 54 - column 2, line 6 see column 3, line 31 - column 4, line 40 see column 4, line 64 - line 66 see claims; examples ----	1,3,4
A	US 5 071 704 A (FISCHEL-GHODSIAN FARIBA) 10 December 1991 see column 3, line 33 - line 40 see column 6, line 58 - column 7, line 42 ----	1,9
A	DE 19 34 710 A (T.J. SMITH AND NEPHEW LTD) 29 January 1970 see page 5, paragraph 5 -----	9



# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 97/23837

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9310201 A	27-05-93	US 5276079 A AT 146212 T AU 657188 B AU 3125493 A CA 2116123 A DE 69215893 D DE 69215893 T EP 0612342 A JP 7501101 T US 5438988 A US 5409966 A US 5389376 A	04-01-94 15-12-96 02-03-95 15-06-93 27-05-93 23-01-97 03-04-97 31-08-94 02-02-95 08-08-95 25-04-95 14-02-95
FR 2734574 A	29-11-96	NONE	
GB 2115431 A	07-09-83	AU 536939 B AU 1058383 A AU 1230288 A CA 1218954 A DE 3305473 A FR 2522006 A JP 1695909 C JP 58162681 A JP 63065235 B JP 1787645 C JP 2211145 A JP 4078310 B US 4699146 A US 4750482 A	31-05-84 29-09-83 26-05-88 10-03-87 02-02-84 26-08-83 28-09-92 27-09-83 15-12-88 10-09-93 22-08-90 10-12-92 13-10-87 14-06-88
EP 0184470 A	11-06-86	US 4593053 A CA 1263783 A JP 1858892 C JP 61179280 A	03-06-86 05-12-89 27-07-94 11-08-86
WO 9614822 A	23-05-96	AU 4282096 A CA 2204777 A EP 0799017 A	06-06-96 23-05-96 08-10-97
WO 9613238 A	09-05-96	AU 3544695 A	23-05-96

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 97/23837

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
W0 9613238 A		CA 2201169 A CZ 9701267 A EP 0788338 A SK 52797 A ZA 9508447 A	09-05-96 14-01-98 13-08-97 08-10-97 07-05-96
US 5559165 A	24-09-96	AU 6190696 A CA 2182713 A EP 0758009 A JP 9125035 A	13-02-97 09-02-97 12-02-97 13-05-97
US 5071704 A	10-12-91	US 5455043 A	03-10-95
DE 1934710 A	29-01-70	BE 735782 A CA 925379 A CH 526306 A DK 127578 B FR 2012584 A GB 1280631 A NL 6910564 A,B, SE 127578 B SE 377887 B US RE31887 E US 3645835 A US RE31886 E	08-01-70 01-05-73 29-09-72 03-12-73 20-03-70 05-07-72 13-01-70 03-12-73 04-08-75 14-05-85 29-02-72 14-05-85